

APR 24 2001

K003558

510(K) Summary for the Siemens TCI-Combi

REVISED 4/16/01

1. **Applicant's Name & Address:** Siemens Hearing Instruments
 10 Constitution Ave.
 PO Box 1397
 Piscataway, NJ 08855

2. **Contact Person, Telephone and
 e-mail Address:** Dave Slavin
 732-562-6658
 dslavin@siemens-hearing.com

3. **Device Trade or Proprietary Name:** TCI-Combi (Tinnitus Control
 Instrument Combination)

4. **Device Common Name /
 Classification Name:** **Hearing Aid, Air Conduction
 and Tinnitus Masker**

 Product Code: **ESD and KLW**

5. **Establishment Registration Number:** 2217809

6. **Address of Manufacturing Site:** Siemens Hearing Instruments
 10 Constitution Ave.
 PO Box 1397
 Piscataway, NJ 08855

7. **Classification of Device:** Class II

8. **Marketed Devices to which the claim of
 substantial equivalence is made:** K 97229
 Siemens Hearing Instruments
 Prisma Hearing Instrument
 & K974751
 General Hearing Instruments
 Tranquil Tri-OE

9. **Compliance with Section 514, Performance Standards:** Not Applicable

10. **Indications for Use:**

The TCI-Combi is a behind-the-ear style electronic, air conduction broad-band noise generator and hearing aid intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. TCI-Combi is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

The target population is primarily the adult population over 18 years of age. The target group for this product includes individuals reporting tinnitus who do need amplification. This product may also be used with children 5 years of age or older.

11. **Description of Device:**

TCI-Combi is a fully digital, low-level noise generator that was developed to be used along with appropriate counseling and/or tinnitus therapy. This product is programmable, with selectable noise and output levels. The output noise can be custom-tailored to the user's individual requirements. The TCI-Combi is also a digital programmable hearing aid which provides sound amplification. This hearing aid is a four-channel instrument with wide dynamic range compression. The product has two programs that can be programmed independently to noise masker only, amplification only or both noise masker and sound amplification. The unit is housed in a conventional behind-the-ear case.

12. **Comparison Information to Predicate Device:**

TCI-Combi is the combination of a tinnitus masker and a conventional hearing instrument. Thus, two devices are specified here as predicate devices. The tinnitus masker portion of the TCI-Combi is predicated by General Hearing Instruments Tranquil Tri-OE. The hearing instrument portion of the TCI-Combi is predicated by Siemens Hearing Instruments Prisma hearing aid.

The TCI-Combi is substantially equivalent to the General Hearing Instruments Tranquil TRI-OE (K974751). The Tranquil is also a noiser for tinnitus, with no amplification characteristics. The Siemens TCI-Combi differs from the Tranquil, in that the TCI-Combi is a digital product with programmable noise characteristics, which increases the flexibility of the device.

The TCI-Combi is equivalent to the Siemens Hearing Instruments Prisma hearing instrument. The programmable hearing instrument parameters of the TCI-Combi are the same as the programmable parameters of the Prisma.

The following table compares the Siemens Hearing Instruments TCI-Combi device to the predicate devices – General Hearing Instruments Tranquil Tri OE and Siemens Hearing Instruments Prisma.

	Siemens Hearing Instrument TCI-Combi Device	Predicate Device: General Hearing Instruments Tranquil Tri OE (GHI) and Siemens Hearing Instruments (SHI) Prisma	
Intended Use	Mask tinnitus as part of tinnitus management program Provide amplification for compensation of hearing loss	Mask tinnitus as part of tinnitus management program (GHI) Provide amplification for compensation of hearing loss (SHI)	
Target Population	Adults and children (≥ 5 years) with tinnitus and hearing loss that are participating in a tinnitus management program	GHI Adults with tinnitus and hearing loss that are participating in a tinnitus management program	SHI Adults and children with hearing loss
Operation Circuit type	Digital	GHI Analog	SHI Digital

Programmable	Yes	No	Yes
Available noises	One	One	
Volume control	Yes	Yes	Yes
Number of channels	Four		Four
Variable compression kneepoint	Yes		Yes
Variable compression ratio	Yes		Yes
Multiple programs/memories	Yes		Yes
Physical Description	Standard behind-the-ear instrument housing	Custom in-the-ear product (GHI)	
		Standard behind-the-ear instrument housing (SHI)	
Output Characteristics			
Noiser	102 dB Broadband noise	75 dB SPL High-tone noise (GHI)	
Hearing aid amplifier	105 dB HF-Average OSPL 90 (ANSI S3.22-1996)	118.5 dB HF-Average OSPL 90 (ANSI-S3.22-1996)	
Volume control range	Programmable: OFF, 8 dB, 16 dB, 32 dB	40 dB	

TCI-Combi Comparison with Predicate Devices

13. Information required under Title 21, Section 874.3400, and not already provided above.

Risks:

The maximum output of the noise masker is 102 dB measured with an A-weighted filter. As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer.

Hearing Healthcare Professional Diagnosis:

The sale and fitting of the Siemens TCI-Combi will only be conducted through a Hearing Healthcare Professional, such as an audiologist or otolaryngologist.

Benefits:

Relief of tinnitus symptoms may be provided by this device when utilized with appropriate counseling and/or tinnitus therapy. Sound amplification may be of benefit to the individual with hearing loss when programmed for the user's hearing loss.

Warnings for Safe Use:

As the noise may be on continuously and as the noise level does fall into the range which can cause hearing loss (OSHA Regulations (Standard – 29 CFR 1910.95 Occupational Noise Exposure)), warnings are included in the Technical Information for the Hearing Health Professional and in the User's Manual for the consumer. General use precautions are in the User's Manual.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dave Slavin, Director
Quality Assurance and Regulatory Affairs
Siemens Hearing Instruments
10 Constitution Avenue
P.O. Box 1397
Piscataway, NJ 08855

Re: K003558
Trade Name: TCI-Combi (Tinnitus Control Instrument Combination)
Regulatory Class: II
Product Code: ESD and KLW
Regulation: 21 CFR 801.420 & 421; 21 CFR 874.3400
Dated: February 20, 2001
Received: February 22, 2001

Dear Mr. Slavin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

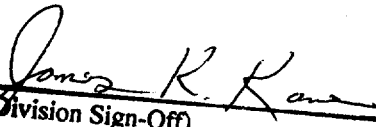
A handwritten signature in black ink, appearing to read "A. Ralph Rosenthal". The signature is fluid and cursive, with the first name "A." and last name "Rosenthal" clearly distinguishable.

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

10. Indications for Use:

The TCI-Combi is a behind-the-ear style electronic, air conduction broad-band noise generator and hearing aid intended to output noise of sufficient intensity and bandwidth to be used for tinnitus habituation therapy and is also suitable for tinnitus masking therapy. TCI-Combi is intended to be used by those individuals who experience tinnitus and desire amplification. This device is fit by a qualified audiologist or other hearing healthcare professional familiar with the diagnosis of tinnitus and subsequent rehabilitation therapy.

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(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K003558

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